IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN FURTHER SUPPORT OF MOTION TO LIMIT THE TESTIMONY OF BRUCE ROSENZWEIG, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this reply in further support of their motion to limit the testimony of Bruce Rosenzweig, M.D.

I. The Court should preclude Dr. Rosenzweig from testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of SUI and POP and/or that Defendants' devices are less safe than those alternatives.

In those jurisdictions in which a plaintiff is required to prove the availability of a feasible, safer alternative product, the Court should preclude Dr. Rosenzweig from testifying about traditional surgical procedures. Plaintiffs have not explained why such testimony would be relevant in those jurisdictions.

II. The Court should preclude Dr. Rosenzweig from providing design opinions and testifying that other synthetic mesh devices are safer alternatives for the surgical treatment of SUI or POP.

Dr. Rosenzweig seeks to apply a different and more lax standard to his opinions regarding Ultrapro (and other semi-absorbable meshes) than he does to his opinions regarding Defendants' devices. Specifically, he attempts to indict Ethicon for launching its devices without having performed "long-term" studies even though Ethicon relied on the best evidence available, while simultaneously heralding Ultrapro (and other semi-absorbable meshes) as a safer

alternative in the absence of long-term studies because Dr. Rosenzweig relied on the much weaker evidence available. That is classic hypocrisy.

Further, Dr. Rosenzweig's reliance on one inapposite article to support his opinions about Ultrapro is far from reliable. *See Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *38 (S.D. W. Va. April 28, 2016) (finding that citation to merely one article in support of opinion was insufficient).

The problem with Plaintiffs' argument can perhaps best be observed in their half-hearted effort to distinguish *Conklin v. Novartis Pharmaceuticals Corp.*, 2012 U.S. Dist. LEXIS 136428 (E.D. Tex. Sept. 18, 2012). The expert in *Conklin* did not, as Plaintiffs suggest, opine that "because safety is better, efficacy is necessarily better." Rather, he offered the same opinion that Dr. Rosenzweig attempts to offer – a lower dose translates into fewer adverse reactions and, therefore, the lower dose is a feasible alternative design. The *Conklin* expert, just like Dr. Rosenzweig here, made no review of the effect that a lower dose would have on the efficacy of the product.

Plaintiffs want Dr. Rosenzweig to be able to testify that a semi-absorbable mesh would reduce adverse effects while maintaining efficacy. Dr. Rosenzweig, however, admits that he lacks the necessary long-term scientific evidence to arrive at this opinion. While Dr. Rosenzweig may have one study of another product to "suggest" that a semi-absorbable mesh could effectively treat stress urinary incontinence, that study is not a "long-term" study of the safety and efficacy of semi-absorbable mesh and, therefore, does not meet Dr. Rosenzweig's own standard for valid scientific evidence regarding the safety and efficacy of the product—the same standard he is attempting to use against Ethicon in this case. Indeed, Plaintiffs cannot escape from the fact that Dr. Rosenzweig himself has testified that he is not comfortable accepting

Ultrapro as a viable alternative in the absence of additional studies. Ex. K to Def's Motion, Rosenzweig 7/13/15 Dep. 174:13-17, 180:17-181:18, 198:8-13.

Moreover, Plaintiffs do not acknowledge that Dr. Rosenzweig cannot identify the polypropylene volume at which efficacy can be obtained and the adverse events avoided. He offers nothing other than the hypothesis that there may exist some form of mesh where the volume of polypropylene is low enough to avoid adverse events but high enough to be sufficiently effective. What that amount is, he does not know. And whether this hypothetical alternative exists he does not know.

The Texas Court of Appeals recently reversed and rendered a lower court judgment, in part, due to a similar issue. In *Johnson & Johnson v. Batiste*, 2015 Tex. App. LEXIS 11517 (Tex. Ct. App. Nov. 5, 2015), the plaintiff argued that her alleged injuries were caused by degradation of the polypropylene mesh in her TVT-O device. Just as Plaintiffs here have done, the *Batiste* plaintiff designated Howard Jordi, Ph.D., as her polymer scientist on the issue of degradation. Dr. Jordi testified that in his opinion the mesh removed from Ms. Batiste showed signs of degradation. The appellate court found that this testimony was insufficient to create a causal connection between the degradation and the plaintiff's alleged injuries because the plaintiff could not demonstrate the "amount of degradation that must occur before it has any clinical significance in a patient, and there is no evidence the mesh that was placed inside of Batiste had degraded to the extent that it caused her injury." *Id.* at 16; *see also id.* at 18 ("[T]here was no evidence that surface degradation of the polypropylene fibers alone causes pelvic pain or of the amount of degradation that would have to occur before there would be any injury to a patient.").

Here, Dr. Rosenzweig cannot offer an opinion regarding the volume of polypropylene that alleged causes adverse events in women. In the absence of such opinion, it would be

improper to allow him to opine that the volume of polypropylene in Ultrapro or any other semi-absorbable mesh is "safer" than the volume of polypropylene in TVT.

Finally, Plaintiffs ignore that there simply have not been any commercially available devices on the market that have a larger pore size than the mesh in Defendants' devices. *See* Ex. A hereto, Rosenzweig 12/22/15 Dep. 289:2-18 [Carlino] (failing to identify any mesh for SUI that has a larger pore size than the mesh in the TVT Devices). Indeed, Plaintiffs fail to acknowledge that Ethicon endeavored to launch a SUI product with Ultrapro mesh, but its cadaver lab tests failed and the FDA rejected Ethicon's 510k application. Ex. B hereto, FDA rejection letter; Ex. C hereto, *Perry v. Luu*, Cal. Superior Ct., No. 1500-cv-279123, Trial Tr. 3293:15-3300:15 (Kern County Fen. 11, 2015). Therefore, Dr. Rosenzweig's proposed alternative was, quite simply, never an option.

III. The Court should limit Dr. Rosenzweig's product warning opinions.

A. Warnings about the frequency, severity, and duration of possible adverse events.

The Court should not allow Dr. Rosenzweig to suggest that Ethicon owed a duty greater than that required by law, such as by asserting that Ethicon's IFUs needed to detail the frequency, severity, and duration of potential risks. *See Smith ex rel. v. Wyeth Labs. Inc.*, 1986 WL 720792, at *9-10 (S.D. W. Va. Aug. 21, 1986). This is an area beyond Dr. Rosenzweig's expertise as a pelvic surgeon and simply does not comport with the law.

B. Opinions about the appropriateness of the devices for certain patient populations are irrelevant and unreliable.

Plaintiffs make no attempt to distinguish these cases from *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 705 (S.D.W. Va. 2014), in which this Court appropriately excluded Dr. Rosenzweig's opinions about "special patient populations."

IV. The Court should preclude Dr. Rosenzweig from testifying about alleged mesh degradation and other biomaterials opinions.

A. Degradation

As an initial matter, when Dr. Rosenzweig uses the term "degradation" he is applying a meaning different from the biomaterials experts in this case. The biomaterials experts use the term degradation to reference the potential for a change in the mesh material at a molecular, microscopic level. Dr. Rosenzweig is using the term "degradation" to describe mesh material that is broken on a macroscopic level (i.e. mesh that is allegedly broken and visible to the naked eye).

Defendants do not argue that Dr. Rosenzweig should be prohibited from discussing his clinical observations. Dr. Rosenzweig claims that he has removed broken mesh from patients. This is his purported clinical experience, and Defendants will deal with those allegations on cross-examination. What he should not be allowed to do, however, is testify that his clinical observations are related to degradation. Dr. Rosenzweig lacks the credentials necessary to form such biomaterials opinions.

Likewise, Dr. Rosenzweig engaged in no methodology to connect his macroscopic observations to any alleged degradation. He should not be permitted to opine that his clinical observations were the result of degradation when he has done nothing to determine same.

Dr. Rosenzweig has no reliable methodology to connect alleged degradation, particle loss, or fraying to adverse events experienced by women. Plaintiffs claim that there are "scientific studies" that "support" Dr. Rosenzweig's opinions. This assertion is incorrect.

Plaintiffs' cite to three documents: (1) Imel, A., *et al.*, In Vivo Degradation of Polypropylene Pelvic Mesh, Biomaterials (2015) ("Imel Article") [Ex. I to Pls' Response]; (2) an internal document: Pelvic Floor Repair – Surgeon's Feed-back on Mesh Concept ("Surgeon

Feedback") [Ex. J to Pls' Response]; and (3) Jeffrey Blitstein, M.D., *et al.*, *A Novel Composite Sling for the Treatment of Stress Urinary Incontinence: First Clinical Experience*, International Congress of the European Hernia Society, presented June 22, 2001 ("Blitstein Article") [Ex. D to Pls' Response]. Doc. 2163, pp. 13-14. First, it is worth noting that Plaintiffs do not argue that Dr. Rosenzweig relied upon any of these three documents to formulate his opinions.

In any event, none of these three documents are "scientific studies" demonstrating that alleged degradation, particle loss, or fraying causes adverse events in women. Examining the documents individually reveals, in addition, that these documents are not what Plaintiffs represent them to be.

The first paper – the Imel Study – did not test TVT Device or Prolene mesh. *See* Ex. I to Pls' Response, Imel Article at 4. Rather, the Imel Article studied the performance properties of Boston Scientific Corporation's Pinnacle and Obtryx pelvic repair meshes. *Id.* More importantly, the Imel Article never concluded that degradation, particle loss, or fraying in the competitor products' mesh caused adverse events in women. *See generally id.*

The second document is not a "scientific study" at all. Instead, it is a collection of hearsay statements recorded in a company document. *See* Ex. J to Pls' response, Surgeon Feedback at 2. The document plainly states that it is a compilation of "[f]eed-back . . . obtained through conversations and interviews with 21 surgeons." *Id.* One surgeon, Dr. Hilton, commented on particle loss – not degradation or fraying – and stated that he was concerned that "[t]he small particles migrate and cause pain during intercourse." *Id.* at 8.

This is not a statement from an Ethicon employee, but rather the statement of a third-party. Plaintiffs are attempting to use it for the truth of the matter asserted. Accordingly, the statement is hearsay. Moreover, not only is it a hearsay statement but it is opinion testimony.

There is no indication in the statement regarding the methodology applied by Dr. Hilton when arriving at that opinion.

In fact, when Dr. Hilton later conducted his own scientific studies on the subject of the safety and efficacy of TVT, he concluded that the product was safe and effective. Ex. D hereto, K. Ward & P. Hilton, *Prospective mutlicentre randomized trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence*, BMJ vol. 325 (July 13, 2002); Ex. E hereto, K.L. Ward & P. Hilton, *Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5- year follow up*, BJOG (Oct. 26, 2007).

The third document cited by Plaintiffs – the Blitstein Article – did not study the mesh from Defendants' devices. Ex. D to Pls' Response, Blitstein Article at 2. Instead, it looked at a semi-absorbable mesh. *Id.* Additionally, the Blitstein article does not conclude that degradation, particle loss, or fraying leads to an adverse event. In fact, the article is silent on degradation, particle loss, and fraying. Plaintiffs cite the Court to a statement in the article regarding curling. But even then, the article does not conclude that curling leads to adverse events in women. Instead, it says that "[t]he mesh [i.e. not TVT but the semi-absorbable mesh studied] will also tend to curl acting as a non-expandable rigid circular bridge." *Id.* at 4.

Notwithstanding the Court's prior rulings, this is the first instance in which the Court has had an opportunity to consider whether Dr. Rosenzweig may competently testify about the clinical effects of alleged degradation. Because Plaintiffs have not shown that there is a reliable foundation for Dr. Rosenzweig's opinions that degradation leads to adverse events in women, the Court should preclude him from offering those opinions at trial.

B. Cytotoxicity

The crux of Plaintiffs' response concerning Dr. Rosenzweig's cytotoxicity opinions is that the Court has previously addressed this issue. While the Court has previously addressed this opinion, new evidence exists regarding Dr. Rosenzweig's "methodology." It is now clear that Dr. Rosenzweig's methodology on the issue of cytotoxicity is inherently flawed and based on nothing more than a logical fallacy. Ethicon respectfully submits that, in the light of this new information, the Court should revisit the issue. Indeed, Plaintiffs are silent on the fact that their own biomaterials experts (Drs. Guelcher, Jordi, and Klinge) do not opine that the mesh in Defendants' devices is cytotoxic. Because Dr. Rosenzweig's opinions appear to be premised on a *post hoc ergo propter hoc* logical fallacy, these opinions should be excluded.

C. MSDS Sheet

According to Plaintiffs, Dr. Rosenzweig's "primary opinions are that the Defendants should have done 'clinically relevant testing' and that physicians should have been warned about the danger of placing this polypropylene in an oxidized area." Doc. 2163, p. 15. As set forth in Section V.A of Defendants' initial brief, Dr. Rosenzweig is not competent to critique Ethicon's testing.

As it relates to Dr. Rosenzweig's warnings component, neither Dr. Rosenzweig nor Plaintiffs have suggested what methodology that Dr. Rosenzweig used at arriving at his opinion that a legitimate danger was presented. Accordingly, these opinions also should be excluded.

V. The Court should preclude Dr. Rosenzweig from testifying about duties allegedly owed by a manufacturer.

A. Testing

Plaintiffs ask the Court to reconsider its prior ruling in *Huskey* that Dr. Rosenzweig is not competent to testify about testing. First, Plaintiffs argue that Dr. Rosenzweig will not opine

about "how a particular test should have been structured," but instead that Ethicon "should have performed testing." Doc. 2163, p. 16. Yet, there is nothing about Dr. Elliott's background as a urogynecologist that would make him competent to testify about the duties owed by a medical device manufacturer to conduct testing.

Further, as this Court has appropriately noted, "[w]hether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct," that are beyond the purview of expert testimony. Ex. M to Def's Motion, *Bellew v. Ethicon, Inc*., No. 2:13-cv-22473, Order at 18 (S.D. W. Va. Nov. 20, 2014). In any event, Dr. Rosenzweig may only speculate improperly about what any hypothetical testing would have revealed. Consistent with its prior rulings, the Court should disallow such testimony.

Plaintiffs also attempt to bolster Dr. Rosenzweig's credentials by discussing experiences that are not set forth in his curriculum vitae provided to Defendants. Aside from the fact that such maneuvering at this juncture is improper, it appears that Dr. Rosenzweig merely performed a clinical role in certain tests that were performed. This does not make him competent to testify about the parameters of a duty of a manufacturer to conduct testing.

B-D. Adverse Event Reporting/Training/Legal Conclusions

Plaintiffs have conceded that Dr. Rosenzweig will not opine about adverse event reporting or training and that he will not provide legal conclusions.

VI. The Court should preclude Dr. Rosenzweig from criticizing the cut of TVT mesh.

Plaintiffs acknowledge that Dr. Rosenzweig is critical of both mechanically-cut mesh and laser-cut mesh. Dr. Rosenzweig should not be allowed to suggest to the jury that his complaints about roping, fraying, and particle loss would be assuaged by laser-cut mesh when he believes that laser-cut mesh is less safe than mechanically-cut mesh. This is yet another example of

claims of a lack of safety based on alternatives which Plaintiffs do not claim would be effective. Dr. Rosenzweig may not reliably suggest that the cutting of the mesh is unsafe if he is unwilling to testify that the other way to cut the mesh is safer.

VII. The Court should preclude Dr. Rosenzweig from testifying about certain alleged complications associated with TVT-Abbrevo.

Notwithstanding the assertions in Plaintiffs' response, Dr. Rosenzweig has cited no studies that support the proposition that TVT-Abbrevo has more complications as a consequence of "the shorter length of the laser cut mesh." Ex. D to Def's Motion, TVT-Abbrevo Report at 13. There simply is far too great of an analytical gap in Dr. Rosenzweig's analysis which is not supported by reliable evidence.

VIII. The Court should not allow other opinions that are beyond Dr. Rosenzweig's expertise and/or otherwise improper.

Plaintiffs make no attempt to explain what special qualifications that Dr. Rosenzweig has that would allow him to opine on the effect of financial bias on the results of medical research.

CONCLUSION

For the foregoing reasons and those set forth in Defendants' initial briefing, Defendants respectfully request that the Court limit Dr. Rosenzweig's testimony in these cases.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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